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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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EXAMINER

MEHTA, ASHWIN D

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1638

28

DATE MAILED: 10/01/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/811,093

Applicant(s)

CLENDENNEN ET AL.

Examiner

Ashwin Mehta

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 July 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,5,7,9-12,15 and 19-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,7,9-12,15 and 19-23 is/are rejected.
- 7) ☒ Claim(s) 5 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 March 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 22, 2003 has been entered.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Specification

3. The amendment filed August 5, 2002 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: SEQ ID NO: 46.

Applicant is required to cancel the new matter in the reply to this Office Action.

As discussed in the paragraph bridging pages 6-7 of the Office action mailed December 11, 2002 and the Office action mailed June 10, 2003 under item 10, SEQ ID NO: 46 sets forth a nucleotide sequence that was determined after the filing of the instant application. This sequence is new matter that must be removed.

4. Claim 5 remains objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim Rejections - 35 USC § 112

5. Claims 1, 7, 9-12, 15, 19, and 20 remain and new claims 21-23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record stated in the Office action mailed June 10, 2003 under item 5. Applicants traverse the rejection in the paper submitted July 22, 2003. Applicants' arguments have been fully considered but were not found persuasive.

Applicants argue that the written description guidelines indicate that the level of skill and knowledge in the art should be considered, and present abstracts of journal articles (Exhibits A-E) that demonstrate that at the time of Applicants' invention, it supposedly was common practice to identify sub-fragments of a promoter region that retain promoter activity (response, paragraph bridging pages 4-5). However, an invention must be described by the specification that presents it, not by one skilled in the art. Further, it is noted that the abstracts of Exhibits B-D indicate that the articles may actually disclose the sequences of the portions of the subject promoter. The articles to which these abstracts belong, therefore, may describe the portions of promoters by

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correlating a structure with a function (It is noted that the full articles were not provided by Applicants, precluding analysis of the full teaching of the cited art). The instant specification, however, does not correlate the structure of any portion of SEQ ID NO: 42 with a function, other than bases 156-1708.

Applicants also argue that claim 1 does not encompass a genus that encompasses widely variant species having different sequences, such as a claim encompassing any promoter sequence capable of inducing fruit-associated expression, and containing 65% identity with the disclosed Mel7 promoter region. Applicants argue that the only difference between members of the species is the amount of extraneous sequence not responsible for the fruit-associated promoter activity (response, page 5, 1st full paragraph). However, it remains that the claim encompasses any portion size of a 1735 bp sequence, no matter how small, having fruit-associated promoter activity. Yet, the smallest fragment of SEQ ID NO: 42 that is correlated by the specification as having fruit-associated expression consists of bases 156-1708. This single species is not representative of all of the species encompassed by the claims. This single species does not give any information about the sequences within it that, alone, would retain the same transcriptional activity. Further, Applicants in the paper submitted May 8, 2003, admit that the specification does not describe sub-fragments of the M

6. Claims 1, 7, 9-12, 15, 19, and 20 remain and new claims 21-23 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a portion of SEQ ID NO: 42 consisting of nucleotides 156-1708 that directs fruit-associated transcription, does not reasonably provide enablement for any other portion of SEQ ID NO: 42 as having the functional

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activity of directing fruit-associated transcription. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, make and/or use the invention commensurate in scope with these claims, for the reasons of record stated in the Office action mailed June 10, 2003 under item 5. Applicants traverse the rejection in the paper submitted July 22, 2003. Applicants' arguments have been fully considered but were not found persuasive.

Applicants argue the examiner has not provided any reasons why guidance must be provided to enable the claims (response, paragraph bridging pages 5-6). However, it is not predictable what portions of SEQ ID NO: 42, other than bases 156-1708, retain fruit-associated promoter activity. In the absence of guidance, one skilled in the art would be left to make fragments of any and all sizes from the 1735 bp sequence of SEQ ID NO: 42, which amounts to undue experimentation. Applicants also argue that the examiner's citing of *Genentech v. Novo Nordisk* was misleading, because the *Genentech* case uses the phrase "novel aspects," and not "enabling aspects" (response, paragraph bridging pages 5-6). However, it remains that the instant specification must teach the novel portions of SEQ ID NO: 42 that retain its fruit-associated transcriptional activity.

Applicants argue that the breadth of the claims is narrow, that every embodiment of the claim contains an promoter sequences that are identical except for the amount of sequence from SEQ ID NO: 42 that is unnecessary for the activity (response, page 6, 2nd full paragraph). However, that breadth of claim 1 fails to encompass other things does not preclude it from being subject to this rejection. The entire breadth of any claim must be enabled.

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Applicants argue that it is highly predictable that one skilled in the art will be able to make fragments of nucleotides 156-1708 of SEQ ID NO: 42 that retain fruit-associated promoter activity (response, page 7, 1st full paragraph). However, one cannot simply predict what portions of bases 156-1708 of SEQ ID NO: 42 would retain this activity without conducting further experimentation. Applicants have not taught how this can be done in the absence of experimentation.

Applicants argue that any skilled molecular biologist could perform a number of standard experiments to identify smaller elements that confer similar functionality, and that the quantity of experimentation is minimal (response, paragraph bridging pages 6-7, and page 7, 2nd and 3rd full paragraphs). However, as the starting nucleotide sequence is over 1700 bp, the quantity of experimentation is not minimal, as discussed above. Further, while Applicants appear to be trivializing this aspect of the invention, it is apparent that not a single portion of SEQ ID NO: 42, other than bases 156-1708, has been shown to have fruit-associated functional activity. It is suggested, if other portions have been determined, that a declaration be submitted, indicating how such portions were determined using the teachings of the specification.

7. Claim 5 is objected to, and claims 1, 7, 9-12, 15, and 19-23 are rejected.

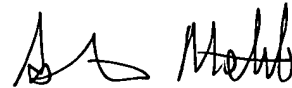
Contact Information

Any inquiry concerning this or earlier communications from the examiner should be directed to Ashwin Mehta, whose telephone number is 703-306-4540. The examiner can normally be reached on Mondays-Thursdays and alternate Fridays from 8:00 A.M to 5:30 P.M.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at 703-306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 and 703-872-9306 for regular communications and 703-872-9307 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

September 29, 2003

A handwritten signature in black ink, appearing to read 'Ashwin D. Mehta'.

Ashwin D. Mehta, Ph.D.
Primary Examiner
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